

TOWNSEND and TOWNSEND and CREW LLP

By: Christopher J. Parker

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Mark G. Erlander, et al.

Application No.: 10/727,100

Filed: December 2, 2003

For: PREDICTING OUTCOME WITH  
TAMOXIFEN IN BREAST CANCER

Confirmation No.: 4395

Examiner: J.S. Sitton

Art Unit: 1634

SECOND SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The additional references cited on attached forms PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of references BA-BJ in compliance with the requirements of 37 CFR §1.98(a)(2) are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, because this submission is prior to the issuance of a first Office Action on the merits.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

  
Kawai Lau  
Reg. No. 44,461

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 858-350-6100  
Fax: 415-576-0300  
KL:tsp  
60781774 v1

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/727,100		
		Filing Date	December 2, 2003		
		First Named Inventor	Erlander, Mark G.		
		Art Unit	1634		
		Examiner Name	J.S. Sitton		
Sheet	1	of	2	Attorney Docket Number	022041-001410US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	AA	US-2003/0219760 A1	11/27/03	Gordon et al.	
	AB	US-			
	AC	US-			
	AD	US-			
	AE	US-			
	AF	US-			
	AG	US-			
	AH	US-			
	AI	US-			
	AJ	US-			
	AK	US-			
	AL	US-			
	AM	US-			
	AN	US-			
	AO	US-			
	AP	US-			
	AQ	US-			
	AR	US-			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AS							<input type="checkbox"/>
	AT							<input type="checkbox"/>
	AU							<input type="checkbox"/>
	AV							<input type="checkbox"/>
	AW							<input type="checkbox"/>

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

60781774 v1

Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/727,100
				Filing Date	December 2, 2003
				First Named Inventor	Erlander, Mark G.
				Art Unit	1634
				Examiner Name	J.S. Sitton
Sheet	2	of	2	Attorney Docket Number	022041-001410US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	BA	HOWELL, Sacha J., et al. "The use of selective estrogen receptor modulators and selective estrogen receptor down-regulators in breast cancer", <i>Best Practice &amp; Research Clinical Endocrinology &amp; Metabolism</i> (2004) 18(1):47-66	<input type="checkbox"/>	
	BB	FABIAN, Carol J., et al. "Short-Term Breast Cancer Prediction by Random Periareolar Fine-Needle Aspiration Cytology and the Gail Risk Model", <i>Journal of the National Cancer Institute</i> (2000) 92(15):1217-1227	<input type="checkbox"/>	
	BC	TAN-CHIU, Elizabeth, et al. "Effects of Tamoxifen on Benign Breast Disease in Women at High Risk for Breast Cancer", <i>Journal of the National Cancer Institute</i> (2003) 95(4):302-307	<input type="checkbox"/>	
	BD	HALL, Julie M., et al. "The Multifaceted Mechanisms of Estradiol and Estrogen Receptor Signaling", <i>The Journal of Biological Chemistry</i> (2001) 276(40):36869-36872	<input type="checkbox"/>	
	BE	LEVENSON, Anait S., et al. "Gene Expression Profiles with Activation of the Estrogen Receptor $\alpha$ -Selective Estrogen Receptor Modulator Complex in Breast Cancer Cells Expressing Wild-Type Estrogen Receptor", <i>Cancer Research</i> (2002) 62:4419-4426	<input type="checkbox"/>	
	BF	JORDAN, V. Craig, et al. "Introducing a new section to <i>Breast Cancer Research: Endocrinology and hormone therapy</i> ", <i>Breast Cancer Research</i> (2003) 5:281-283	<input type="checkbox"/>	
	BG	DAUVOIS, Sophie, et al. "Antiestrogen ICI 164,384 reduces cellular estrogen receptor content by increasing its turnover", <i>Proc. Natl. Acad. Sci.</i> (1992) 89:4037-4041	<input type="checkbox"/>	
	BH	WILLSON, T.M., et al. "Dissection of the Molecular Mechanism of Action of GW5638, a Novel Estrogen Receptor Ligand, Provides Insights into the Role of Estrogen Receptor in Bone", <i>Endocrinology</i> (1997) 138(9):3901-3911	<input type="checkbox"/>	
	BI	WIJAYARATNE, Ashini L., et al. "Comparative Analyses of Mechanistic Differences Among Antiestrogens", <i>Endocrinology</i> (1999) 140(12):5828-5840	<input type="checkbox"/>	
	BJ	DUTERTRE, Martin, et al "Molecular Mechanisms of Selective Estrogen Receptor Modulator (SERM) Action", <i>The Journal of Pharmacology and Experimental Therapeutics</i> (2000) 295(2):431-437	<input type="checkbox"/>	
	BK		<input type="checkbox"/>	

Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.